K010126

MAR 12 2001

510 (k) Summary

SUBMITTER:

Submitted on behalf of:

Manufacturer: CL-TINTERS

Address: Hoylaamotie 7
Fin-00380 Helsinki
Finland

Phone: 358 9340 5066

CONTACT PERSON: **Martin S. Knopf**

DATE SUMMARY PREPARED: **January 12, 2001**

TRADE NAME: **Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted)**

COMMON NAME: **contact lens**

SUBSTANTIALLY EQUIVALENT TO:

The PROSTHETIC (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) is substantially equivalent to the Company's cast molded PROSTHETIC (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted), pursuant to K984259 and the lathe cut Gelflex Alpha (polymacon) Hydrophilic Contact Lens for Daily Wear which is manufactured for CL-TINTERS. This lens received marketing clearance pursuant to K940848. These predicate lenses are currently marketed in the U.S.

Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) are substantially equivalent to the indications for use of the lathe cut Gelflex Alpha (polymacon) Hydrophilic Contact Lens for Daily Wear which is manufactured for CL-TINTERS pursuant to K940848. The only addition to these indications are that the subject lens is also indicated to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris or lens abnormalities. In addition, Gelflex Laboratories, Ltd. will produce the dry lathe cut lenses at the same manufacturing location as the predicate devices. These lenses are subsequently processed by CL-TINTERS to incorporate the pigments (i.e., listed color additives) to produce their unique tinting patterns.

This lens is in Group 1, non-ionic, low water content polymers as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition

May 1994. The physical, optical, and chemical properties of the Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) are equivalent to those of the lathe cut Gelflex Alpha (polymacon) Hydrophilic Contact Lens for Daily Wear.

DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA crosslinked with EGDMA, which yield the appearance of lenses, which are designed to fit over the corneal surface of the eye. The lenses are made by modifying the uncolored polymacon cast molded lens by affixing a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of: carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue and titanium dioxide. These lenses are designed with varying base curves, which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power that is to correspond to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens that is generally of a diameter greater than 6mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

INDICATIONS FOR USE:

Device Name: Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted)

Prosthetic (polymacon) Hydrophilic Contact Lens (clear and tinted) is indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

Performance Testing of Contact Lens

Lenses were loaded with the following eleven pigments (i.e., listed color additives):

Carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue and titanium dioxide.

The results of toxicology testing (cytotoxicity, acute systemic toxicity and acute ocular irritation) have demonstrated that the subject lens is non toxic. Furthermore, the results of residual monomer and color leachability testing demonstrate that the respective extracts did not contain leachable color or significant levels of residual monomers.

The physical optical, and chemical properties of the Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted) are equivalent to those of the lathe cut Gelflex Alpha (polymacon) Hydrophilic Contact Lens for Daily Wear since this lens is provided to CL-TINTERS by Gelflex Laboratories, Ltd.

PARAMETERS AVAILABLE:

PROSTHETIC™ (polymacon) Hydrophilic Contact Lens (clear and tinted)

Chord Diameter:	12.0mm to 16.0mm
Center Thickness:	0.03mm to 0.40mm
Base Curve:	7.80mm to 9.60mm
Powers:	-20.00 Diopters to +20.00 Diopters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2001

CL-Tinters
c/o Mr. Martin S. Knopf
President and CEO, Knopf Associates, Inc.
10 Warrenton Lane
Colts Neck, NJ 07722

Re: K010126
Trade Name: Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear
(clear and tinted, lathe-cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: January 12, 2001
Received: January 16, 2001

Dear Mr. Knopf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS STATEMENT

Device Name: Prosthetic (polymacon) Hydrophilic Contact Lens for Daily Wear (clear and tinted)

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____

Eric C, PhD

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010126